



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

1038 '01 APR 13 P3:21
MAR 30 2001

Ms. Maggie Li
Vice President
Tianshi Health Products, Inc.
728-134th Street, SW
Suite 222
Everett, Washington 98204

Dear Ms. Li:

This is in response to your letter of March 16, 2001 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Tianshi Health Products, Inc. is making the following claim, among others, for the product Tianshi High Absorption Calcium Drink:

“...maintain a healthy blood sugar level...”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, cure, or mitigate disease, namely disorders of blood glucose levels. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-3 10, 7520 Standish Place, Rockville, Maryland 20855.

975 0163 LET 476

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Please contact us if we may be of further assistance.

Sincerely,

for 

John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Seattle District Office, Office of Compliance, HFR-PA340

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cc:

HFA-224

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-8 10 (Foret)

HFS-8 11 (Moore, w/original incoming)

HFD-40 (Behrman)

HFD-3 10

HFD-3 14 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

GCF- 1 (Nickerson)

r/d:HFS-8 11:RMoore:3/27/01

docname:75073.adv:disc55



TIANSHI
HEALTH PRODUCTS INC.

25073

March 16, 2001

Dr. Elizabeth Yetley
Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, D.C. 20204

MAR 20 2001

RE: Notification of Product Claims

Dear Dr. Yetley:

This letter serves as a notification of the nutritional **support** label statements being made by Tianshi Health Products, Inc., located at 728 - 134th Street SW, Suite #222, Everett, WA 98204, in connection with the marketing of its line of dietary supplements. A list of the products and their respective nutritional support statements are listed in the attached Exhibit "A".

Tianshi **Health** Products, Inc. certifies that the information contained in this notice is complete and accurate, and that the company maintains documentation to substantiate that its product claims are truthful and not misleading.

If you have any questions, please feel **free** to contact the undersigned.

Sincerely,

Maggie Li
Vice President
Tianshi Health Products, Inc.

2. Product: Tienshi High Absorption Calcium Drink (Cal II)

A dietary supplement containing:

1. Bio-calcium powder
2. Defatted milk powder
3. Inulin (chicory root based)
4. Soluble dietary fiber
5. Pumpkin powder
5. Cocoa
6. Ethyl maltol
7. Butter essence
8. Vanilla
9. Vitamin A
9. Vitamin D
10. Vitamin C
11. Vitamin B1
12. Vitamin B2

Statements of Nutritional Support:

1. 100% natural high absorption calcium
2. Contains chicory root based inulin, a good source of soluble fiber, to help promote and maintain healthy bowel function and provide relief from occasional constipation.
3. Tienshi Cal II is formulated to help maintain a healthy blood sugar level.